DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Hitachi Medical Systems America, Inc.
% Mr. Doug Thistlethwaite
Manager of Regulatory Affairs
1959 Summit Commerce Park
TWINSBURG OH 44087

September 30, 2015

Re: K150565
Trade/Device Name: Supria Whole-body X-ray CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: August 26, 2015
Received: August 27, 2015

Dear Mr. Thistlethwaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150565

Device Name

HITACHI Supria Whole-body X-ray CT System

Indications for Use *(Describe)*

The Supria system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages. The images can be acquired in either axial, helical, gated or dynamic modes.

The volume datasets acquired by the Supria can be post processed by the system to provide additional information and can be transferred to external devices via a DICOM standard interface.

Post processing capabilities included in the Supria software include CT angiography (CTA), Multi-planar reconstruction (MPR) and volume rendering.

The device output can provide an aid to diagnosis when used by a qualified physician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Section 5

510(k) Summary

Submitter Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
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Date:	February 12, 2015

Device Name

Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Product Code	JAK, System, X-Ray, Tomography, Computed
Class	II
Panel	Radiology
Trade/Proprietary Name:	Supria Whole-body X-ray CT System
Predicate Device(s):	SCENARIA Phase 2 Whole-body X-ray CT System (K123509)

Device Intended Use

The Supria system is indicated for head, whole body, and vascular X-ray Computed Tomography applications in patients of all ages. The images can be acquired in either axial, helical, or dynamic modes.

The volume datasets acquired by the Supria can be post processed by the system to provide additional information. Post processing capabilities included in the Supria software include CT angiography (CTA), Multi-planar reconstruction (MPR) and volume rendering.

Volume datasets acquired by the Supria can be transferred to external devices via a DICOM standard interface.

The device output can provide an aid to diagnosis when used by a qualified physician.

Device Description

Function

The Supria is a multi-slice computed tomography system designed to perform multi-slice CT scanning supported by 16-detector technology. The system allows optimum clinical applications ranging from routine exams in response to the diversified circumstances in imaging whole body regions.

Scientific Concepts

The Supria system uses 16-slice CT technology, where the X-ray tube and detector assemblies are mounted on a frame that rotates continuously around the patient using slip ring technology. The solid-state detector assembly design collects up to 16 slices of data simultaneously. The X-ray sub-system features a high frequency generator, X-ray tube, and collimation system that produces a fan beam X-ray output. The system can operate in a helical (spiral) scan mode where the patient table moves during scanning. As the X-ray tube/detector assembly rotates around the patient, data is collected at multiple angles.

The collected data is then reconstructed into cross-sectional images by a high-speed reconstruction sub-system. The images are displayed on a Computer Workstation, stored, printed, and archived as required. The workstation is based on current PC technology using the Windows™ operating system.

Physical and Performance Characteristics

The Supria system consists of a Gantry, Operator's Workstation, Patient Table, High-Frequency X-ray Generator, and accessories. The system performance is similar to the predicate device.

Performance Comparison

A clinical evaluation comparison was conducted with the Supria system and the SCENARIA Phase 2 System (K123509) and found to be substantially equivalent.

In addition, evaluations were conducted for dose profile, image noise, Modulation Transfer Function (MTF), slice thickness and sensitivity profile, slice plane location, and CT dose index and also found to be substantially equivalent.

A rationale analysis was then conducted and the results are contained in Table 1.

Table 1 Performance Comparison Analysis

Testing Type	Rationale Analysis
Performance Testing - Clinical	We provide six clinical image examples which we judged to be sufficient to judge a clinical usability. The six covered the general anatomy outlined in the indications for use and are comparable to the anatomy examples provided for the Predicate with the exception of cardiac images due to the fact that the Supria does not support imaging with ECG. In addition, a radiologist validated that clinical images which applied image quality optimization technology (Intelli IP Advanced and IntelliEC) have acceptable image quality for clinical use.
Performance Testing - Bench	We generated bench data based on IEC61223-3-5. We confirmed that the items (Dose Profile, Noise, Mean CT number and Uniformity, Sparial Resolution, Tomographic Section Thickness and Sensitivity Profile, Tomographic Plane Location, CT dose index) which we tested met the conditions of 21 CFR 1020.33(c) or (g). This shows that Supria has equivalent basic performance as the predicate device, SCENARIA Phase2.

The analysis confirms the performance characteristics of the Supria are comparable to the predicate device and support our conclusion that the Supria system is substantially equivalent.

Device Technological Characteristics

The technological characteristics of the Supria and the predicate device are listed in Table 2.

Table 2 Technological Characteristic Differences

ITEM	HITACHI Supria 16 Slice	HITACHI SCENARIA PHASE 2 (K123509)	Difference Analysis
Gantry			
Geometry	Rotate-rotate with offset detector system, slip ring	Rotate-rotate with offset detector system, slip ring	No
Scan Time	0.75, 1.0, 1.5, 2.0 [s]	0.35, 0.4, 0.5, 0.75, 1.0, 2.0 [s]	Table 2: 01
X-ray Fan Beam Angle	51 [deg]	51 [deg]	No
Gantry Tilt	-30 to +30 [deg]	-30 to +30 [deg]	No
Gantry Aperture	750 [mm]	750 [mm]	No
Gantry Dimensions	1990 x 920 x 1842.5 [mm]	2350 x 880 x 2030 [mm]	Table 2: 02
Gantry Weight	1600 [kg]	2235 [kg]	Table 2: 02
Scan Localizer	Laser	Laser	No
Detector			
Type	Solid state	Solid state	No
Number of Channels	880 [ch] (8ch reference)	888 [ch] (8ch reference)	Table 2: 03
Number of Rows	16	64	Table 2: 03
Number of Slices	16 [slice/scan] (Axial)	64, 128 [slice/scan] (Axial)	Table 2: 03
X-ray Tube			
Anode Heat Storage	5 [MHU]	7.5 [MHU]	Table 2: 04
Dissipation Rate	748 [kHU/min]	1,386 [kHU/min]	Table 2: 04

ITEM	HITACHI Supria 16 Slice	HITACHI SCENARIA PHASE 2 (K123509)	Difference Analysis
Tube cooling	Oil/air	Cooling Fluid/air	Table 2: 04
Tube focal spot	Dual 0.7 x 0.8, 1.2 x 1.4 [mm]	Dual 0.7 x 0.8, 1.2 x 1.4 [mm]	No
X-ray Generator			
kW Output	System Maximum 48[kW] / Generator Maximum 51 [kW]	72 [kW]	Table 2: 05
Max. Power Input	75 [kVA]	100 [kVA]	Table 2: 05
kVp Range	80, 100, 120, 140 [kVp]	80, 100, 120, 140 [kVp]	No
mA Range	10 to 400 [mA] @120kV, 48kW	10 to 600 [mA] @120kV, 72kW	Table 2: 05
Patient Table			
Range of Movement, Vertical	450 to 1000 [mm] (CT-WT-21)	465 to 1050 [mm] (CT-WT-19) 450 to 1050 [mm] (CT-WT-18L)	Table 2: 06
Range of Movement, Longitudinal	1910 [mm] (CT-WT-21)	2110 [mm]	Table 2: 06
Range of Movement, Lateral	N/A	-80 to +80 [mm] (CT-WT-19)	Table 2: 06
Scannable Range	155 cm	175 cm	Table 2: 06
Maximum Load Capacity	227 [kg]	230 [kg]	Table 2: 06
Display			
Monitor Type	24" LCD	24" LCD	No
Matrices, Pixels	1920 x 1200	1920 x 1200	No
Image Enlargements	Up to 9.99x	Up to 9.99x	No
Max. Slices Displayed at Once	25	25	No
Image Storage			
Hard Disk	110 [GB] (images), 200 [GB] (raw data)	250 [GB] (images), 750 [GB] (raw data)	Table 2: 07
Storage Images	200,000	200,000	No
Archival Storage (Media)	DVD-R/RW, CD-R/RW	DVD-RAM, DVD-R/RW, CD-R/RW	Table 2: 07
Scanning, Reconstruction			
Localization Scan	Real time	Real time	No
Localization Scan Length	150, 250, 350, 500, 750, 1000, 1250, 1500, 1750 [mm]	150, 250, 350, 500, 750, 1000, 1250, 1500, 1750 [mm]	No
Max. Scan Time	100 [s]	100 [s]	No
Helical Beam Pitch	0.56, 0.81, 1.06, 1.31, 1.56	0.58, 0.83, 1.08, 1.33, 1.58 @40mm Collimation	Table 2: 08
Collimation	1.25, 5, 10, 15, 20 [mm]	1.25, 5, 10, 15, 20, 40 [mm]	Table 2: 08
Reconstruction Matrix	512 x 512 [pix]	512 x 512 [pix]	No
Reconstruction FOVs	20 to 500 [mm]	20 to 500 [mm]	No
Slice Thickness	0.625, 1.0, 1.25, 2.5, 3.75, 5.0, 7.5, 10.0 [mm]	0.625, 1.0, 1.25, 2.5, 3.75, 5.0, 7.5, 10.0 [mm]	No
Range of CT numbers	-2000 to +4000 (13bit) -32768 to +32767 (16bit)	-2000 to +4000 (13bit) -32768 to +32767 (16bit)	No
Reconstruction Time	0.1 seconds per image or less	0.056 seconds per image or less	Table 2: 09
Performance			
High-contrast spatial resolution	0.35 [mm]	0.35 [mm]	No
Low-contrast resolution mm at % at ≤4 rads	2.5 [mm] @ 0.25%	2.5 [mm] @ 0.25%	No
10% MTF	14.7 [lp/cm]	14.7 [lp/cm]	No
50% MTF	12.2 [lp/cm]	12.2 [lp/cm]	No
Dose Controls			
Bow Tie Filter	Yes. Normal	Yes. Small / Normal	Table 2: 10
Automatic Exposure Control	Yes. IntelliEC	Yes. IntelliEC	No
Longitudinal Modulation	Yes	Yes	No
Angular Modulation	Yes	Yes	No
Iterative Reconstruction	Yes. Intelli IP Advanced Mode	Yes. Intelli IP Advanced Mode	No

ITEM	HITACHI Supria 16 Slice	HITACHI SCENARIA PHASE 2 (K123509)	Difference Analysis
Maximum possible pitch with full image quality	1.56	1.58	Table 2: 11
Dose Displays			
CTDIv	Yes	Yes	No
DLP	Yes	Yes	No
Features			
Axial Scan	Yes	Yes	No
Helical Scan	Yes	Yes	No
Dynamic Scan	Yes	Yes	No
Predict Scan	Yes	Yes	No
ECG Retrospective Scan (Helical)	No	Yes	Table 2: 12
ECG Prospective Scan (Axial)	No	Yes	Table 2: 12
guideShot Scan	No	Yes	Table 2: 13
Automatic Exposure Control	Yes.	Yes. IntelliEC	No
Automatic Exposure Control using Iterative Reconstruction	No.	No.	No
ECG Dose Modulation	No	No.	No
Adaptive Filter	No	Yes. Intelli IP Normal	Table 2: 14
Iterative Reconstruction	Yes. Intelli IP Advanced	Yes. Intelli IP Advanced	No
Injector Synchronization	Yes	Yes	No
Dose Check	Yes	Yes	No
Access Control	Yes	No	Table 2: 15
Automatic Cardiac Phase Search	No	Yes. CardioHarmony	Table 2: 12
Preview Scan	No	No	No
Double Slice at Axial Scan	No	Yes. Fine Recon	Table 2: 16
Priority Recon.	No	No	No
Dose Report	Yes. Simple Dose Report	Yes. Simple Dose Report	No
DICOM	Yes	Yes	No
ID Reader	Yes	No	Table 2: 17
Exam Split	Yes	No	Table 2: 18
Multi-Planar Reconstruction (MPR)	Yes	Yes	No
Volume Rendering	Yes	Yes	No
CT Angiography (CTA)	Yes	Yes	No
Segmentation	Yes	Yes	No
Retouch	Yes	Yes	No
Quality Exam	Yes	No	Table 2: 19

The differences from the predicate device to Supria are explained in Table 3.

Table 3 Analysis of Differences

Gantry	
01	Because the specifications of the device are different, the minimum scan time of this device is not as short as the Predicate. This change does not affect overall technological characteristics compared to the Predicate.
02	Because the specifications of the device are different, the size and the weight of the Gantry of this device are different from the Predicate. However, as the device weighs less and has a smaller footprint than the Predicate, we judge that these changes do not impact the intended use.
Detector	
03	Because the number of provided slices for one rotational scan is different per equipment specifications, there are fewer number of detectors and number of the channels than the Predicate.

X-ray Tube	
04	The X-ray tube of this device is different from Predicate only in heat capacity. The X-ray tube focal spot and general performance characteristics are the same as the Predicate.
X-ray Generator	
05	The X-ray generator was selected to match the performance specifications of this device and conforms to IEC60601-2-44-2009 requirements for CT systems. The kVp and mA output of the device is comparable to the Predicate.
Patient Table	
06	The scannable range specification was defined assuming the number of the provided slices by one rotational scan is approximately 25% of Predicate, and the table travel and weight capacity specifications are generally equivalent to the Predicate.
Image Storage	
07	The data output volume of this device is approximately 25% of Predicate and the volume of the hard disk drive (HDD) was defined to give an equivalent exam capacity as the Predicate. In addition, we select commonly available external output media that is both easy to obtain and meets the device specification requirements.
Scanning, Reconstruction	
08	The helical scan pitch specification is based on the table movement distance and collimation width, but is nearly identical to the Predicate.
09	The data processing load of this device is approximately 25% of Predicate and the computing capacity was defined to achieve an equivalent performance specification compared to the Predicate.
Dose Controls	
10	While this device is not equipped with a small Bow-Tie Filter, the normal Bow-Tie Filter provides generally equivalent performance to the Predicate and does not substantially impact the effectivity and safety of this device.
11	As noted above, the pitch specification is only marginally different and therefore does not substantially alter the device performance as compared to the Predicate.
Features	
12	This device is a general purpose CT system that is not equipped with an ECG function. The lack of ECG does not substantially affect the intended use of the device and does not impact the effectivity and safety of this device as compared to the Predicate.
13	This device is a general purpose CT system that is not equipped with the guideShot option for in-room image viewing. The lack of guideShot does not affect the intended use of the device and does not impact the effectivity and safety of this device as compared to the Predicate.
14	This device is not equipped with an Adaptive Filter function, but has an Iterative Reconstruction feature which provides an equivalent image processing function.
15	This function is intended to confirm device performance according to IEC 62351-8 and NEMA XR-26.
16	This device is not equipped with a Fine Recon function which does not impact the effectivity and safety of this device.
17	This function supports the input of patient information by a bar code reader.
18	This function is for dividing one examination into multiple examinations (with unique Accession numbers) as an operator convenience.
19	This function is intended to confirm device performance according to IEC 61223-3-5/IEC 61223-2-6.

Therefore, based on a thorough analysis and comparison of the Supria and the predicate device, the technological characteristics do not impact safety and effectiveness.

Substantial Equivalence

A summary decision was based on analysis of Table 4.

Table 4 Rationale Analysis: Supria vs. Predicate

ITEM	Overall Rationale Analysis
Gantry	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics. The gantry and detector design was based on the same technology as the Predicate. These sub-systems have the same level of general effectiveness as the Predicate based on the performance test results shown in Section 10. For safety, these items are controlled and tested according to same regulations and/or standards as the Predicate.
Detector	
X-ray Tube	
X-ray Generator	This item conforms to IEC60601-2-44-2009 requirements for CT systems and has the same level of general effectiveness as the Predicate based on the performance test results shown in Section 10. For safety, this item is controlled and tested according to same regulations and/or standards as the Predicate.
Patient Table	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics. The table travel and weight capacity characteristics are generally equivalent to the Predicate. For safety, this item is controlled and tested according to same regulations and/or standards as the Predicate.
Display	There are no functional differences in this item.
Image Storage	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics. The design criteria for these elements were set to allow comparable performance to the Predicate. The performance of these sub-systems does not substantially affect the effectivity and safety as compared to the Predicate and were verified by design V&V.
Scanning, Reconstruction	
Performance	There are no substantial differences in this category based on the performance test results shown in Section 10.
Dose Controls	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics. For safety, these items are controlled and tested according to same regulations and/or standards as the Predicate.
Dose Displays	There are no functional differences in this item.
Features	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics and the feature set of the device is generally equivalent to the Predicate.

Therefore, based on a thorough analysis and comparison of the functions, scientific concepts, physical and performance characteristics, performance comparison and technological characteristics, the proposed Supria Whole-body X-ray CT System is considered substantially equivalent to the currently marketed predicate device (SCENARIA Phase 2 Whole-body X-ray CT System K123509) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Summary of Non-Clinical Testing

The Supria system is in conformance with the applicable parts of the following standards:

- AAMI ANSI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012

  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 3: 2007

  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-3 Edition 2.0 2008-01

  Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-44 Edition 3.0 2009-02

  Medical electrical equipment Part 2-44: particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography.
- NEMA XR 25 Computed Tomography

  Dose Check
- NEMA XR26

  Access Controls for Computer Tomography: Identification, Interlocks, and Logs
- IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes

In addition, the device complies with all applicable requirements for Dose Profile, Noise, Mean CT number and Uniformity, Spatial Resolution, Tomographic Section Thickness and Sensitivity Profile, Tomographic Plane Location, and CT dose index.

Summary of Clinical Testing

Clinical images were collected and analyzed, to ensure that images constructed by the Supria Whole-body X-ray CT System meet user needs.

As a result of the analysis:

Testing Type	Rationale Analysis
Performance Testing - Clinical	We provide six clinical image examples which we judged to be sufficient to judge a clinical usability. The six covered the general anatomy outlined in the indications for use and are comparable to the anatomy examples provided for the Predicate with the exception of cardiac images due to the fact that the Supria does not support imaging with ECG. In addition, a radiologist validated that clinical images which applied image quality optimization technology (Intelli IP Advanced and IntelliEC) have acceptable image quality for clinical use.

Conclusions

Hitachi believes that, based on the information included in the submission, Supria Whole-body X-ray CT System is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the SCENARIA Phase 2 Whole-body X-ray CT System (K123509).